DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thermo Fisher Scientific
c/o Bola Nicholson
Technical and Operations Manager
171 Industry Drive
Pittsburgh, PA 15275-1034

SEP - 4 2007

Re: k070531
Trade/Device Name: ISE Module for the DataPro™ Plus
Regulation Number: 21 CFR 862.1170
Regulation Name: Chloride Test
Regulatory Class: Class II
Product Code: CGZ, CEM, JGS
Dated: July 03, 2007
Received: July 09, 2007

Dear Bola Nicholson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070531

Device Name: ISE Module for the DataPro™ Plus

Indications for Use: The ISE module of the DataPro™ Plus Clinical Chemistry Analyzer is intended for the quantitative determination of **sodium, potassium and chloride in serum,** using ion-selective (ISE) electrodes.

Sodium: Disorders of the sodium ion (Na^+) can be caused by excessive loss, gain or retention of Na^+ or excessive retention of water. Low Na^+ can be associated with renal failure, congestive heart failure and cirrhosis. An increase in Na^+ is seen in neurological disorders such as tremors, ataxia, confusion and coma.

Potassium: Disturbances of potassium (K^+) homeostasis has serious consequences and can lead to tachycardia when low. When high, respiratory weakness peripheral vascular collapse and cardiac arrest is evident. It is also seen in conditions associated with Addison's disease. Levels higher than 10mmol/L are fatal in most cases.

Chloride: When the chloride ion (Cl^-) is unbalanced in the serum, it is usually a sign of an underlying disturbance in fluid and acid-base homeostasis. A low Cl^- concentration is observed in individuals with salt-losing nephritis whereas an increase in Cl^- can indicate acute renal failure and metabolic acidosis.

The ISE module, and all of the reagents included in this test system are for in vitro diagnostic use only.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070531